

Dangerous and Hypnotic Drug Act

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IN 1945, California enacted the Dangerous Drug Law. Said to be the most comprehensive regulatory measure concerning control of hypnotic drugs,¹ it is a part of the Pharmacy Law and is administered by the State Board of Pharmacy.

Section 4211 of the Business & Professions Code defines *Dangerous and Hypnotic Drugs*:

"'Dangerous Drug': 'Hypnotic Drug.' 'Dangerous drug' means any drug unsafe for self-medication, except preparations of drugs defined in subdivisions (e), (f), (h), and (i) hereof, designed for the purpose of feeding or treating animals (other than man) or poultry, and so labeled, and includes the following:

"(a) Any hypnotic drug. 'Hypnotic drug' includes acetyluric derivatives, barbituric acid derivatives, chloral, paraldehyde, sulfonmethane derivatives, or any compounds or mixtures or preparations that may be used for producing hypnotic effects.

"(b) Aminopyrine, or compounds or mixtures thereof.

"(c) Amphetamine, desoxyephedrine, or compounds or mixtures thereof except preparations for use in the nose and unfit for internal use.

"(d) Cinchophen, neocinchophen, or compounds or mixtures thereof,

"(e) Diethyl-stilbestrol, or compounds or mixtures thereof.

"(f) Ergot, cotton root, or their contained or derived active compounds or mixtures thereof.

"(g) Oils of croton, rue, savin or tansy or their contained or derived compounds or mixtures thereof.

"(h) Sulfanilamide or substituted sulfanilamides, or compounds or mixtures thereof, except preparations for topical application only containing not more than 5 per cent (5%) strength.

"(i) Thyroid and its contained or derived active compounds or mixtures thereof.

"(j) Phenylhydantoin derivatives.

"(k) Any drug which bears the legend: 'Caution: federal law prohibits dispensing without prescription.'

"(l) Hypnotic drugs when combined and compounded with non-hypnotic drugs."

• It is unprofessional conduct within the meaning of the Medical Practice Act to prescribe a dangerous drug without either a medical examination by a physician or other medical indications.

Dangerous and hypnotic drugs are specifically defined by both state and federal law and distribution is strictly regulated.

A physician may administer to his own patients such amounts of dangerous drugs as are necessary for the immediate needs of the patient. The physician may obtain such needed amounts of these drugs by an order placed with a pharmacist marked "for administration to immediate needs of patients." A licensed physician may also prescribe dangerous and hypnotic drugs for patients and such prescriptions may be refilled on the specific authorization of the physician.

A physician who dispenses dangerous and hypnotic drugs to patients must obtain a hypnotic drug license; he must use specific purchase orders when purchasing; the drugs must be labeled in the manner provided by law; and all records of sale shall be open to inspection by authorized officers of the law and kept for three years.

By the Principles of Medical Ethics physicians are bound to limit the source of their professional income to medical services actually rendered. Recent decisions of the Judicial Council answer questions concerning a physician's interest in a corporation which purchases, packages and sells medicines under a corporate name. Also answered are questions as to the measures that exist to prevent physicians from abusing the privilege of owning a pharmacy, and whether a physician can ethically rent space in a building owned by him to a pharmacist with a percentage of the income of the pharmacy as rental.

The public welfare of California and the nation as determined by legislation strictly regulates the distribution of dangerous drugs. It is in the best interest of the medical profession and its patients that these laws be understood and carefully observed.

The Federal Food, Drug and Cosmetic Act (FFDC) defines and regulates narcotic and hypnotic drugs by prohibiting, among other things, the *misbranding* of them. Section 502(d) provides that a drug shall be deemed to be misbranded—

"If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde,

¹The Narcotic Problem, edited by W. L. Prosser, 1 U.C.L.A. Law Review 405-546.

peyote, or sulfonmethane; or any chemical derivatives of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement 'Warning—May be habit forming.'"

The problem of addiction caused by the use of narcotics has been recognized for centuries. Sedatives or hypnotics are drugs recently developed. Chloral hydrate is said to be the oldest. It was discovered in 1832 and introduced into medicine in 1869 by Liebreck. A German scientist, in 1907, discovered derivatives of barbituric acid while working with coal tar. Winthrop & Co. brought the drug Veronal, a barbiturate, to this country in 1907. It was not until after World War I that any large production of barbiturates was begun in this country.

The misuse of them has presented serious problems in recent years. Among habitual users, these drugs are called: *red birds, red devils, yellow jackets, brownies, green dragons, blue bombers, violets and goofballs.*

There is a lively dispute among authorities as to whether the hypnotic drugs are properly classified as addictive. In public policy of the State of California, hypnotic drugs are classified as dangerous and their distribution is strictly regulated.

It is well established that a state, in the exercise of its police power, may regulate and control the manufacture, sale, distribution and possession of drugs in the interest of public health and welfare.²

Section 4051 of California's Business & Professions Code provides that this "chapter" of the law which concerns licensing of pharmacists and manufacturers of drugs "does not apply to or interfere with anyone who holds a physician's and surgeon's certificate or certificate to practice chiropody and who is duly registered as such by the Board of Medical Examiners or the Board of Osteopathic Examiners of this State, with supplying his own patients with such remedies as are necessary in the treatment of the condition for which he attends such patient if he acts as their physician and is employed by them as such and provided such person keeps accurate records of drugs dispensed and that such drugs may not be dispensed by a nurse or attendant."

The Dangerous and Hypnotic Drug Law, by Section 4226, provides: "This article does not require a license from and shall not apply to or interfere with a physician, dentist, chiropodist or veterinarian in administering hypnotic drugs to his own patients. Such hypnotic drugs shall be administered only by the physician, dentist, chiropodist or veterinarian."

²Minn. ex rel Whipple v. Martinson 256 U. S. 41 (1920).
In re Yun Quong 159 Cal. 508, 114 Pac. 835 (1911).

Section 4226 is an exception to Section 4222 which provides that "every person who furnishes any hypnotic drug to any other person shall first obtain from the board [State Board of Pharmacy] an hypnotic license."

Section 4213 defines the word *administer* as used in the article to mean "the furnishing by a physician and surgeon, dentist, chiropodist or veterinarian *to his patient* of such amount of drugs or medicines referred to in this article *as are necessary for the immediate needs of the patient.*" "Administering" and "furnishing" drugs for the "immediate needs" of the patient would appear to be different from "dispensing" or prescribing for the general need of the patient. An exact definition of a patient's "immediate needs" is not provided by the law. But each physician, where furnishing dangerous drugs for the immediate needs of the patient, ought to use some reasonable rule of thumb such as twelve hours or twenty-four hours or some minimal dosage as his standard of judgment of what constitutes sufficient dangerous drugs for the immediate needs only of his patient.

After Section 4226 was enacted, the State Board of Pharmacy asked the Attorney General³ whether a practitioner "who administers hypnotic drugs to a patient will be required to obtain a hypnotic drug license and purchase hypnotic drugs upon hypnotic drug purchase order form."

In answer to this question, the Attorney General considered three different situations:

A. *Administration of Hypnotic Drugs to His Own Patients*

When a physician administers, to his own patient, such amounts of hypnotic drugs as are necessary for the *immediate needs* of the patient, he is not required to have a hypnotic drug license or required to purchase those hypnotic drugs upon a hypnotic drug purchase order form.

Rule 1745 of the State Board of Pharmacy provides that a pharmacy may furnish to a physician and those others named in the law, hypnotic drugs for "*administration to patients*" upon an order showing the date, address, license classification, name of the practitioner and the name, type, strength and quantity of hypnotic drugs ordered. Such order should bear the words: "For Administration to Immediate Needs of Patients" or words of like intent. Such orders are placed by the pharmacist in a special file.

The Attorney General further ruled that there is no requirement that a physician keep a separate record of the hypnotic drugs purchased or supplied to his patients which are necessary for their immediate needs. Good medical practice would dictate,

³18 Opinions Attorney General Cal. 209.

however, that the physician record in the patient's clinical record the hypnotic drugs administered.

It should be emphasized that hypnotic drugs shall be administered only by the physician, dentist, etc. There is only one exception to this: In any licensed or county hospital, a registered nurse, on order and direction of a physician, may administer hypnotic drugs to a patient registered in the hospital or to a patient under emergency treatment in the hospital, in accordance with Section 4225. In a hospital, a special record must be kept of the administration of hypnotic drugs, showing the amount given, the type, date given and the name and address of the person to whom administered. The law does not specifically require it, but sound administration would dictate that the name of the physician who ordered the drug and the registered nurse who administered it also be recorded. This section authorizes a hospital that does not employ a pharmacist to purchase a supply of hypnotic drugs on a hypnotic drug purchase order form in the name of the hospital.

Authority granted in this section is to "licensed or county hospitals not employing pharmacists." Section 4047 excludes from the term "licensed hospital," nursing homes, maternity homes, rest homes, sanatoriums or lying-in asylums. Such establishments would not appear to have authority to order and have on hand a supply of hypnotic drugs, unless they employed a pharmacist. It is understood that some of these facilities make a contract with a local pharmacist in order to provide a supply of needed hypnotic drugs.

B. Dispensing or "Purchase Order Practitioner"

Another means of furnishing hypnotic drugs is outlined in Section 4222: "Every person who furnishes any hypnotic drug to any person shall first obtain from the board [State Board of Pharmacy] an hypnotic license, etc." The board, under Section 4223, shall supply at cost a book of serially numbered triplicate hypnotic drug purchase order forms to physicians and others licensed under 4222.

The physician adopting this procedure is usually referred to as a "purchase order practitioner." He is not limited in the amount of hypnotic drugs he may purchase on an order form, nor is he restricted to furnishing an amount sufficient only for the immediate need or use of his patient.

Due to the dangerous character of hypnotic drugs, a physician should only furnish such amounts as are reasonably necessary for the condition for which he attends his patient.

Section 4228 provides that no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the date, name and address of furnisher and person for whom

prescribed, and directions for use. The section specifically applies to dangerous drugs dispensed "upon prescription." Does it apply only to dispensing by a druggist upon prescription, or does it apply also to dispensing by a physician upon his own unwritten prescription? The advice to a physician on this point is: Follow the provisions of this act. Because of the wording of the statute, you might not technically be convicted of violating the criminal provisions of the act if you did not properly label dangerous drugs furnished, but good public policy and sound medical practice dictate that you should observe the precautions of the law concerning labeling dangerous drugs you dispense.

Section 4224 provides the method by which a physician who dispenses hypnotic drugs shall order them. The purchase order forms furnished by the State Board of Pharmacy to licensees are filled out in triplicate showing the date, name of supplier, name and quantity of hypnotics ordered and signature, license number and address of licensee. The original and one copy of this form are sent to the supplier, who must forward the duplicate copy to the State Board of Pharmacy within thirty days, and the third copy is kept by the physician for three years. If the drugs are purchased out of state, then the original is sent to the supplier and the duplicate is sent directly to the State Board of Pharmacy.

Recently, the attorney general of an eastern state uncovered an extensive counterfeit drug operation which was nationwide in scope. Analysis showed that well-known brand names were affixed to products that were not up to standard and were harmful in some instances. The counterfeiting was so skillful that some drugs could not be recognized as bogus except by chemical analysis. These drugs were "bargains" sold at less than regular prices by an alleged jobber.

Physicians who are *furnishing or dispensing* by sale hypnotic drugs in quantities greater than for the immediate needs of patients, are assuming certain legal and practical responsibilities which must be well understood.

C. Furnishing by Prescription

The third method by which a physician may furnish dangerous hypnotic drugs to his patients is by prescription, after examination of the patient or upon medical indication therefor. It is unprofessional conduct within the meaning of the Medical Practice Act to prescribe a dangerous drug without either a medical examination by the physician or other medical indication. This would be construed by the courts to mean that ordinarily a medical examination of a patient must be made before a dangerous drug is prescribed. However, other medical indications also give him authority to prescribe dangerous drugs.

If a patient is in the hospital, a nurse or intern might report facts of an emergency nature upon which a physician could reasonably prescribe immediately needed dangerous drugs. Physicians associated together are frequently familiar with the medical problems of each other's patients, even though each might not have examined all of the other's patients. In emergencies and when they serve for one another on days off or at times of sickness or vacation, one of them might be called upon to prescribe for an associate's patient whom he had not examined. Yet from information available to him through the office records and consultation, he might have sufficient medical indication to prescribe a dangerous drug in an emergency. These examples are given as guides as to what is meant by the words "medical indication" and not as a limitation on the meaning of them.

The impression might be gained from recent articles appearing in print that a physician could comply with the law that he must examine the patient or that there must be a medical indication for the use of drugs prescribed merely by asking if the patient is nervous or by asking him to stick his tongue out.

However, the Board of Medical Examiners in applying the above requirement of the Medical Practice Act has administered it strictly and realistically. Any physician guilty of subterfuge to cover up the peddling of narcotics invariably has the book thrown at him, and in suspicious circumstances the mere showing of an entry on the physician's record that a patient needed narcotics is viewed with skepticism.

It has often been contended before the Board that a "physician's glance" could tell that a man was sick and needed narcotics. This contention has never impressed the physicians on the Board. The record of the Board indicates that it has not been fooled by phony, inadequate physical examinations or trifling medical indications. It can be expected that the Board would hear expert testimony from other physicians on the medical question: Were the drugs prescribed shown to be necessary by either a medical examination or other medical indications?

Drugs may not be dispensed by a nurse or attendant and may only be prescribed by a physician, dentist, chiroprapist or veterinarian, according to sections 4051 and 4227.

Section 503(b) of the FFDC Act exempts from its labeling and packaging provisions a drug intended for use by man, such as those described in Section 502(d), when:

1. Such drug is administered by or under the supervision of a licensed practitioner; or
2. Such drug is dispensed only upon a written prescription of a practitioner licensed by law to administer such drugs.

This section provides specifically: "The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

In a recent case, the court has applied the provisions of Section 503 to the act of dispensing drugs by a licensed physician when such drugs were not properly labeled or packaged.⁴ In this case, Federal agents had purchased barbiturates from Doctor Brown. He was arrested. At his trial the jury found him guilty of dispensing misbranded drugs contrary to the provisions of Section 503. The case was appealed and the appellate court affirmed the decision of the trial court. Part of the opinion follows:

"There seems to be some concept among members of the medical profession that to have a license to deal in medicine carries a license to deal in barbiturates. That is not the law. The medical profession might just as well understand it. If I come to you for treatment and you in your medical capacity examine me, and after examination determine that certain barbiturates would be beneficial to me, then you have a right to write a prescription to me and then I have a right to get them and use them but not otherwise."

REFILLING PRESCRIPTIONS

Section 4229 provides that no prescription for any dangerous drug may be refilled except upon authorization of the prescriber. The authorization may be given orally, or it may be given at the time of the original prescription.

A prescription refill can only be authorized by the prescriber, such as a physician, either orally or in writing. A nurse or attendant is not authorized to order a prescription refill, but may relay an authorization given by the physician.

STOCKS OPEN FOR INSPECTION

Section 4231 provides that all stocks of any dangerous drug of a physician and the others mentioned in the Act "shall be at all times during business hours open to inspection by authorized officers of the law." Sections 4232 provides that all records of sale or disposition of dangerous drugs shall be open to inspection and be preserved for three years. Ordinarily, such records will not be examined unless there is an indication that the Dangerous Drug Act is being intentionally violated or disregarded.

VIOLATION PENALTY

Violation of any provisions of the Dangerous Drug Act is a misdemeanor punishable by fine or imprisonment. Upon conviction of a physician, he would be subject to having his license to practice revoked or suspended by the State Board of Medical Examiners.

⁴Brown v. U. S. [Texas, 1958] 250 F 2d 745.

As a matter of information, under Section 4163 of this law, a report must be made to the State Board of Pharmacy when chemical examination of tissue or an organ or body fluid shows the presence of poison. Details concerning the poison must also be reported.

For the fiscal year 1958-59, the coroners' offices of the State reported 666 cases distributed as follows:

	No. Cases	Per Cent of Total
Hypnotic drugs	428	64
Tranquillizing drugs	19	3
Industrial, agricultural and household....	106	16
Narcotics	41	6.2
Carbon monoxide	48	7.2
Miscellaneous drugs	24	3.6

Many of these were cases of intentional suicide or attempts at self-destruction. Perhaps if drugs had not been used, some other means would have been employed. Data on cases of this kind are often used to illustrate to the public the dangerous nature of and the need for strict control of hypnotic drugs.

It is doubtful that such a conclusion could be supported in fact or logic. For example, the suicide rate in San Francisco is almost double that of Los Angeles, a difference that hardly can be ascribed to the availability of drugs.

PRINCIPLES OF MEDICAL ETHICS

The American Medical Association's Principles of Medical Ethics provide: "In the practice of medicine a physician should limit the source of his professional income to medical services actually rendered by him, or under his supervision, to his patients. . . . Drugs, remedies or appliances may be dispensed or supplied by the physician provided it is in the best interests of the patient."

Recently, several questions concerning ethical problems relating to a physician's interest in a drug corporation, proper measures to prevent abuse of the privilege of owning such an interest, and rentals by a physician of store space to a pharmacy with a rental based on percentage of income, were answered by the Judicial Council.*

QUESTION: Is it ethically permissible for a physician to have an interest in a corporation which purchases, packages, and sells medicines under a corporate name? Is it permissible for a group of physicians to form a corporation for such a purpose?

ANSWER: It is not *in itself* unethical for a physician or a group of physicians to own or invest in the stock of a pharmaceutical company. The *Principles of Medical Ethics*, as recently as June, 1954, contained the statement "an ethical physician does not engage in barter or trade in the appliances, devices or remedies prescribed for patients, but limits the sources of his professional income to professional services rendered the patient."

*The Judicial Council has authorized the publication of the opinions.—Edwin J. Holman, Secretary.

In June, 1954, the *Principles of Medical Ethics* was revised to provide in this regard: "It is unethical for a physician to participate in the ownership of a drugstore in his medical practice area unless adequate drugstore facilities are otherwise unavailable . . ."

In June, 1955, the *Principles of Medical Ethics* was revised again to provide that "it is *not* unethical for a physician to prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patient."

At the June, 1957, Annual Session of the American Medical Association the present *Principles of Medical Ethics* was adopted. Section 7 of the *Principles* provides that "drugs, remedies or appliances may be dispensed or supplied by the physician provided it is in the best interest of the patient."

In opinions published in *The Journal* (March 30, 1957, and Nov. 15, 1958) the Judicial Council, interpreting this principle of medical ethics, expressed the opinion that the physician as a citizen has the right to make investments according to his own best judgment and that the fact that he is a physician should not preclude him from investing in the stock of a pharmaceutical company, provided, of course, that no subterfuge is employed and no unusual control of the company is exercised by the doctor. The Council also expressed the opinion that it is not, in itself, unethical for physicians to own pharmacies, provided there is no exploitation of the patient.

QUESTION: What measures exist to prevent doctors from abusing the privilege of owning a pharmaceutical company or an interest in it?

ANSWER: In its opinions published in *The Journal* (March 30, 1957, and Nov. 15, 1958) and in its report to the House of Delegates at the Clinical (Dallas) Meeting in 1959, the members of the Judicial Council agreed that there are many variations of this practice. There are, therefore, many questions of fact to be resolved locally before a particular practice can be evaluated properly.

If a complaint is made regarding the practices of a particular physician or a group of physicians who own a pharmaceutical company, the local medical society has a positive obligation. The society must ascertain *whether the practice exploits the patient, whether it results in inferior medical care, whether the costs of drugs to the patient are increased, whether the situation is an act in derogation of the dignity and honor of the medical profession and its traditions, whether the particular practice is a subterfuge to permit the doctor to accept a rebate, whether it tends to cause the doctor to overprescribe or prescribe less effective drugs, or whether the practice permits the doctor to exercise control over the company so as to work against the best interests of the patient.*

The members of the Judicial Council agree that any complaint against a physician or group of physicians who own a small pharmaceutical company should be directed to the local medical society for investigation of the facts and for initial disposition of the ethical question involved. *Neither intentional nor inadvertent abuse of the privilege should be permitted by the medical profession.*

QUESTION: May a doctor who is owner of a building rent space in that building as a pharmacy, with a percentage of the income of the pharmacy as rental?

ANSWER: No. The rental should be a fixed one. Were the rental to be based on the amount of business, it might well be argued, and, indeed, be the case, that fee splitting existed. In addition, the temptation would be ever present for the doctor-owner to encourage patients to take their prescriptions to that pharmacy. The evils inherent in such practice are too obvious to be mentioned.